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Amendment
Attorney Docket No. S63.2B-11023-US01

Amendments To The Drawings:

The attached 3 sheets of replacement drawings include changes to Figures 2-4 and replace original drawing sheets 2-4.

Figure 2 has been amended to show the externally tapered head. See page 6, line 10.

Figure 3 has been amended to show reference numeral 14, representing a crimping apparatus.

Figure 4 has been amended to change reference numeral 10 to 14.

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Remarks

This Amendment is in response to the Office Action dated **January 9, 2006**.

Claims 1-48 are pending in this application. Claims 44-48 have been withdrawn. The Office Action objected to the drawings and specification for formalities, objected to the claims for being misnumbered and objected to claims 3, 5, 7, 8, 10, 11, 14, 17 and 19-24 for being dependent upon a rejected base claim. The Office Action rejected claims 1, 2 and 4 under 35 USC § 102 over White et al. (US 6171234; hereinafter "White"); rejected claims 1, 4, 6, 9, 12, 13, 16, 18 and 43 under 35 USC § 102 over Penner et al. (US 5725519; hereinafter "Penner"); rejected claims 12, 13, 15 and 43 under 35 USC § 102 over Ching et al. (US 6510722; hereinafter "Ching"); rejected claims 25-35, 38, 39 and 41-43 under 35 USC § 102 over Austin (US 6360577). The Office Action also rejects claims 36, 37 and 40 under 35 USC § 103 over Austin.

By this Amendment, claims 1; 4, 12-15, 25 and 43 are amended for clarification purposes. Applicants reserve the right to prosecute any and all cancelled subject matter in a subsequent patent application claiming priority to the immediate application. The specification and drawings are amended to obviate the Office Action's objections. No new matter has been added. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Restriction Requirement

Applicants acknowledge the provisional election of Group I, claims 1-43, drawn to a crimping apparatus. Applicants acknowledge the withdrawal of claims 44-48 as drawn to a non-elected invention.

Applicants note however that in addition to those species identified in the Office Action, additional species may exist which are described in the specification and claims, and which are not subject to the restriction requirement identified by the Office Action.

Specification and Drawings

The Office Action objects to the specification and to the drawings.

The specification is amended in accordance with the Office Action's suggestions to obviate the objections, including changing the reference character for a crimping apparatus

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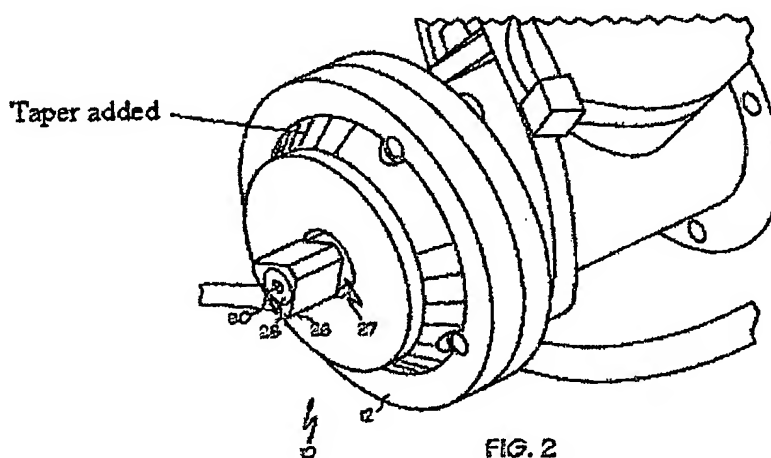
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from 10 to 14. Reference characters previously included in the application have also been added in several locations. The paragraph beginning at page 7, line 18 has further been amended to correct a minor error. No new matter has been added.

The drawings are also amended to obviate the objections. The attached 3 sheets of replacement drawings include changes to Figures 2-4 and replace original drawing sheets 2-4.

Specifically, Figure 3 has been amended to add reference numeral 14, representing the crimping apparatus. Figure 4 has been amended to change reference numeral 10 to 14.

Figure 2 has also been amended to show the externally tapered head, as shown below. The amendment to Figure 2 is supported by the specification as filed, see page 6, line 10, and the tapered portion is also shown in Figure 3 as filed.



Accordingly, Applicants request withdrawal of the objections to the specification and to the drawings.

Allowable Subject Matter

Applicants acknowledge the Office Action's indication of allowable subject matter in claims 3, 5, 7, 8, 10, 11, 14, 17 and 19-24. However, for the reasons set forth below, Applicants respectfully assert that all of the claims are patentable over the applied references, and the application is in condition for allowance.

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Claim Objections

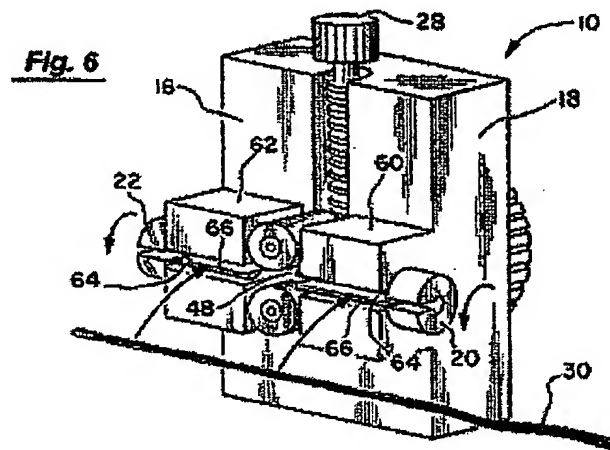
The Office Action indicated that claims 5-49 as filed were misnumbered, as the application inadvertently omitted claim 4.

Applicants thank the Examiner for renumbering the misnumbered claims as 4-48, and for changing the claim dependencies accordingly.

Claim Rejections - White

The Office Action rejects claims 1, 2 and 4 under 35 USC § 102 over White (US 6171234). Independent claim 1 has been amended and recites, "An apparatus for loading a self-expanding stent into a catheter delivery system."

White discloses a device for loading a flexible member 30, such as an imaging core, into a catheter. See Abstract, column 3, lines 32-50, etc. Figure 6 of White is provided below for convenience.



White does not disclose stents except for a teaching that the catheter body may be a stent delivery catheter. White does not disclose a self-expanding stent, as required by claim 1. Therefore, Applicants assert that claim 1 is patentable under 35 USC § 102 over White.

Claim 2 depends from independent claim 1 and is therefore patentable over White for at least the reasons discussed with respect to claim 1.

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Formerly dependent claim 4 has been amended and is now an independent claim that recites "an introducer shaft having an internal lumen for receiving said catheter delivery system."

The Office Action asserts that White discloses "an introducer shaft (not labeled in fig. 6) attached to knob (28)." See Office Action page 5, and Figure 6 of White, provided above.

Reference numeral 28 refers to a regulator assembly relevant to the amount of gap 48 between the rollers 12, 14. See column 4, lines 27-60 and Figs. 5-5B.

Applicants assert that the alleged introducer shaft as described in the Office Action does not have an internal lumen for receiving the catheter delivery system, as required by claim 4.

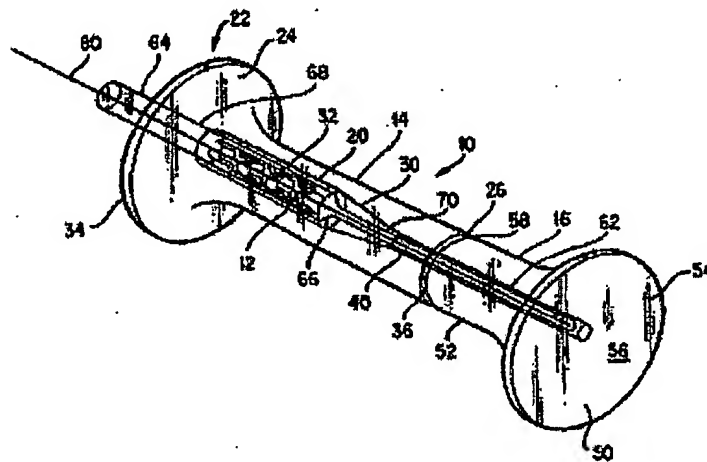
Therefore, Applicants assert that independent claim 4 is patentable under 35 USC § 102 over White.

Accordingly, Applicants request withdrawal of the rejections under 35 USC § 102 over White.

Claim Rejections - Penner

The Office Action rejects claims 1, 4, 6, 9, 12, 13, 16, 18 and 43 under 35 USC § 102 over Penner (US 5725519). These rejections are traversed.

Penner discloses a "stent loading device for a balloon catheter." See title.



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A stent 12 is positioned over the inflation balloon of a balloon catheter and drawn through the device. As the stent 12 passes through the conical portion 30, it is swaged or crimped onto the balloon and catheter. See e.g. column 3, lines 14-34; column 5, lines 40-50. Thus, the Penner device crimps a balloon expandable stent onto a balloon catheter, wherein the stent is oriented around the outside of the inflation balloon, and thus around the outside of the catheter.

Independent claims 1, 4, 12, 16 and 43 include limitations directed to an apparatus for loading either a “medical device” or a “self-expanding stent” “into a catheter.”

Penner does not disclose or suggest loading a medical device into a catheter, for example wherein the medical device is oriented within an internal lumen of the catheter as depicted in Applicants’ Figure 3.

Therefore, Applicants assert that Penner does not disclose or suggest all of the limitations of independent claims 1, 4, 12, 16 or 43, and said claims are patentable under 35 USC § 102 over Penner. Claims 6 and 9 depend from independent claim 4, claim 13 depends from independent claim 12, and claim 18 depends from independent claim 16. The dependent claims are patentable over Penner for at least the reasons discussed with respect to the independent claims from which they depend.

Accordingly, Applicants request withdrawal of the rejections under 35 USC § 102 over Penner.

Claim Rejections - Ching

The Office Action rejects claims 12, 13, 15 and 43 under 35 USC § 102 over Ching (US 6510722).

Ching discloses a “stent crimping tool for producing a grooved crimp.” See title. The device is capable of producing crimps that “deform the stent so that it engages the balloon material to create regions of high frictional resistance between the metal struts of the stent and the expandable member of the stent delivery catheter.” See column 3, lines 25-40. Thus, Ching is directed to a crimper for producing a specialized crimp designed to hold a balloon expandable stent in place on an inflation balloon catheter.

Claim 12 recites a combination of a crimping apparatus and “a loading apparatus

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for introducing said medical device into a catheter delivery system, the crimping apparatus comprising an internal taper constructed and arranged to matingly engage an external taper on the loading apparatus.”

Ching does not disclose or suggest a loading apparatus capable of introducing a medical device into a catheter, for example wherein the medical device is oriented within an internal lumen of the catheter as depicted in Applicants’ Figure 3. Ching further does not disclose or suggest the required external taper on such a loading apparatus.

Therefore, Applicants assert Ching does not disclose or suggest all of the limitations of independent claim 12, and claim 12 is patentable over Ching under 35 USC § 102. Claim 13 depends from claim 12 and is therefore patentable over Ching for at least the reasons discussed with respect to claim 12.

Claim 43 similarly recites an apparatus comprising a “crimping portion” and a “loading portion for loading said medical device into a catheter.” Claim 43 further requires the loading portion to have an internal lumen, and the apparatus to be “constructed and arranged for coaxial self-alignment between the crimping aperture and the internal lumen.”

Ching does not disclose a loading portion suitable for loading a medical device into a catheter, and further does not teach or suggest any coaxial self-alignment between a crimping chamber and a loading portion.

Therefore, Applicants assert Ching does not disclose or suggest all of the limitations of independent claim 43, and claim 43 is patentable over Ching under 35 USC § 102.

Accordingly, Applicants request withdrawal of the rejections under 35 USC § 102 over Ching.

Claim Rejections - Austin

The Office Action rejects claims 25-35, 38, 39 and 41-43 under 35 USC § 102 over Austin (US 6360577). The Office Action also rejects claims 36, 37 and 40 under 35 USC § 103 over Austin.

Independent claim 25 has been amended and recites, “An apparatus for reducing ...and loading the medical device into a catheter...the loading portion having a tapered internal lumen.”

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Austin discloses a stent crimping device, but does not teach loading a medical device into a catheter using a loading portion having a tapered internal lumen.

Therefore, Applicants assert Austin does not disclose all of the limitations of independent claim 25, and claim 25 is patentable over Austin under 35 USC §§ 102 & 103. Claims 26-42 depend from claim 25 and are therefore patentable over Austin for at least the reasons discussed with respect to claim 25.

Independent claim 43 recites, "An apparatus comprising a crimping portion...and a loading portion for loading said medical device into a catheter... the loading portion having an internal lumen...the apparatus constructed and arranged for coaxial self-alignment between the crimping aperture and the internal lumen.

Austin does not teach a device that is constructed and arranged for coaxial self-alignment between the crimping aperture and the internal lumen of a loading portion

Therefore, Applicants assert Austin does not disclose all of the limitations of independent claim 43, and claim 43 is patentable over Austin under 35 USC §§ 102.

Accordingly, Applicants request withdrawal of the rejections under 35 USC § 102 and 35 USC § 103 over Austin.

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Conclusion

Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-43 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: March 30, 2006

By: _____


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